

REMARKS

Claim Status

Claims 14-15, 18, and 29-31 remain pending and are presented for reconsideration.

Claim for Priority

The Advisory Action at page 2 states, "This application is a CIP of 09/577,147, now issued as U.S. Patent No. 6,372,234." As confirmed in the Petition Decision mailed May 12, 2004 (copy attached), and as discussed during the telephone interview of November 3, 2005, the present application properly claims priority to U.S. Application No. 09/448,755, filed November 24, 1999(now abandoned).

Applicants respectfully request that the Examiner acknowledge that the application claims priority to U.S. Application No. 09/448,755, in accordance with the Petition Decision.

Rejections under 35 U.S.C. § 103(a)

Claims 14-15, 18, and 29-31 remain rejected over Moloney *et al.*, Wieles *et al.*, van Rooijen *et al.*, and Murphy *et al.* Advisory Action, pages 2-3. Applicants respectfully traverse.

The Supreme Court recently addressed the proper standard for obviousness in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007). There, the Court held that the proper question for evaluating obviousness is "whether there was an apparent reason to combine the known elements in the fashion claimed." *KSR*, 127 S.Ct. at 1741. The Federal Circuit considered the "reason" requirement in *Takeda Chem. Indus., Ltd. v. Alphapharm Pty, Ltd.*, 492 F.3d 1350, 1356 (2007), reversing an obviousness finding when the claims recited a specific chemical compound and "the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation." The court emphasized that obviousness requires that the prior art give a reason or motivation to make the specific composition claimed. *Takeda*, 492 F.3d at 1356.

Thus, for a proper combination of references, there must be some indicative teaching or suggestion in the prior art. MPEP § 2142. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP § 2143.01.

Here the PTO fails to provide an adequate reason to combine the cited references in the manner asserted. Furthermore, even if there were a suggestion that implicated such a combination, the combined teachings would not have led to the claimed method, because all of the claim recitations are not found in the asserted combination. *See* MPEP § 2143.03.

The PTO alleges that “Moloney *et al.* (WO 93/21320) teach a method of producing a fusion protein by introducing in a plant cell, a chimeric polynucleotide comprising a polynucleotide that regulates transcription in a cell linked to a polynucleotide encoding a fusion protein comprising a portion of an oleosin obtained from plant and a heterologous protein of interest which is further linked to a polynucleotide capable of terminating transcription in a plant cell making a chimeric polynucleotide comprising a polynucleotide capable of regulating transcription in a cell linked to a polynucleotide encoding a fusion protein comprising a portion of an oleosin obtained from a plant and a heterologous protein of interest....” Final Office Action, page 6. On the other hand, the PTO admits “Moloney *et al.* does not teach a method of emulsifying the washed oil bodies comprising the fusion protein, wherein the heterologous protein is a thioredoxin or a thioredoxin reductase and the “portion of an oleosin” is the central domain of an oleosin wherein the fusion protein is produced in a rapeseed cell.” *Id.*, page 4.

Yet, as Applicants have previously explained, Moloney *et al.* fails not only to teach “emulsifying the fusion protein comprising a thioredoxin or thioredoxin reductase” but also fails to disclose formulating into an emulsion a washed oil body preparation that comprises a “recombinant fusion polypeptide,” as recited in the instant claims.

Combining Moloney *et al.* with Wieles *et al.* does not cure the acknowledged deficiencies of Moloney *et al.* Wieles *et al.* is cited for teaching “polynucleotides encoding a thioredoxin and thioredoxin reductase.” Final Office Action, page 4, paragraph 3. Like

Moloney *et al.*, however, Wieles *et al.* fails to teach formulating a washed oil body preparation into an emulsion, as recited in the instant claims. Thus, no permutation of Wieles and Moloney could render the presently claimed invention obvious.

The PTO resorts to van Rooijen, *et al.*, alleging that the reference discloses “oil-bodies, which comprise the heterologous-oleosin fusion protein, remain intact after aqueous extractions, which is equivalent to “washing” the oil bodies.” Advisory Action, page 3. However, combining Moloney *et al.* and Wieles *et al.* with van Rooijen, *et al.* still fails to suggest the present invention.

Like Moloney *et al.* and Wieles *et al.*, van Rooijen *et al.* also fails to teach “emulsifying the fusion protein comprising a thioredoxin or thioredoxin reductase” and does not suggest formulating into an emulsion a *washed* oil body preparation that comprises a recombinant fusion polypeptide, as recited in the instant claims.

The PTO also turns to Murphy *et al.*, for allegedly disclosing that “oleosins act as emulsifying agents and/or as emulsion-stabilizing agents.” Advisory Action, page 3. However, combining Moloney *et al.*, Wieles *et al.* and van Rooijen, *et al.* with Murphy *et al.* yet again fails to suggest the present invention.

Murphy *et al.* discloses that oleosins have a central hydrophobic domain, but is otherwise of little relevance to the claimed invention. Again, Murphy *et al.* neither teaches nor suggests formulating into an emulsion a washed oil body preparation that comprises a recombinant fusion polypeptide, as claimed. Indeed no cited reference or combination thereof teaches or suggests this aspect of the claimed invention. Thus, the obviousness rejection is improper and should be withdrawn.

The PTO incorrectly combines Murphy *et al.*, with Moloney *et al.*, Wieles *et al.*, and van Rooijen *et al.* in the prior art context of producing a fusion protein comprised of at least the central domain of an oil body protein, plus thioredoxin or thioredoxin reductase. Advisory Action, page 3. Invoking a motivation to formulate the fusion protein into an emulsion to increase the stability of the fusion protein such that it could be reused in catalysis, the PTO alleges that one of ordinary skill would have a reasonable expectation for (a) producing the

fusion protein in a plant cell; (b) isolating the fusion protein ; and (c) formulating the fusion protein into an emulsion. *Id.*

Even if the present invention contemplated producing a “recyclable” fusion protein by formulating it into an emulsion, the PTO’s own rationale still would fall short of the claimed invention. As recited in the instant claims, the present invention provides a method for preparing an emulsion formulation by (1) obtaining intact oil bodies; (2) washing the intact oil bodies before preparing an emulsion; and (3) formulating the washed oil body preparation comprising substantially intact oil bodies into an emulsion. No reasonable permutation of teachings from the cited references suggests an emulsion formulation according to the present invention. Thus, the cited references do not disclose each aspect of the present invention and, therefore do not establish a *prima facie* case of obviousness.

For at least these reasons, the §103 rejection is improper and should be withdrawn.

CONCLUSION

Applicant believes that the application is in condition for allowance, and an early notice to that effect is earnestly solicited. Should there be any questions regarding this submission, or should any issue remain, the Examiner is invited to contact the undersigned by telephone in order to advance prosecution.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

By Stephen A. Bent
Reg No 37,288
Stephen A. Bent
Attorney for Applicant
Registration No. 29,768

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicants hereby petition for any needed extension of time.
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